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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,882	12/27/2001	Dale R. Pfost	P-OD 5078	2031

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/034,882	Pfost
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 13, 2003* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above, claim(s) *28-59* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant elected Group I, corresponding to claims 1-27, with traverse. The traversal is on the ground(s) that there is no burden in examining the claims of Groups I to IV together. This is not found persuasive because as the restriction makes clear, additional searches of Groups II-IV would require review not only of 1280 patents in class 536 , subclass 22.1 for Group I but also 16106 patents in class 435, subclass 6 of Group II, 2435 patents in class 424, subclass 88 of Group III and 560 patents in class 700, subclass 90 of Group IV. Review of these additional searches is prima facie evidence of burden which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the composition of compounds effective for treating any pathology associated with single nucleotide polymorphism (SNP). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Court in re Wands, 8 USPQ2d 1400 (CA FC 1988) stated with regard to enablement that

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

Here, the claim is broadly drawn to any composition of compounds which are effective to treat any pathological condition in any subject of any species having SNP in any gene(s). However, the specification does not provide guidance commensurate in scope with this claim, teaching no working example of any efficacy of SNP treatment. The specification provides minimal guidance regarding modulating the activity of at least one target molecule associated with one or more SNP(s). There is no working example of any therapeutic treatment or drug trial and its efficacy in any patients of any animal species (including human) associated with the presence of

any real SNP in any gene. Examples I and II merely proposes some hypothetical designing of compounds that might be effective in SNP. Examples I and II does not provide any statistical significance (p-values calculated by student's t-test). In absence of any practical, meaningful experiment with significant data demonstrating the efficacy of therapeutic composition, it is unclear whether the applicant had actual possession of the composition of compounds as claimed. Moreover, the degree of uncertainty and unpredictability of SNP treatment with drugs is very high as Yu et al. (U.S. Patent 6,593,092 B2) (July 15, 2003) states, "Individuals with a SNP in codon 16 of the beta2 adrenergic gene, however, may not respond to such therapies due to a conformational, or other, change in the receptor that causes a decrease in the affinity between the receptor and the medication or hormone (Column 1, lines 45-49)". It is highly unpredictable whether or what other treatments would function in the context of a conformational, or other, change in the receptor that causes a decrease in the affinity between the receptor and the medication or hormone due to several SNPs (of the beta2 adrenergic gene for example), in different human population and different animal species. Further, composition of two or more compounds treatment regiment will be by the trial and error method. This trial and error requirement is borne out because effects of drug therapy on any disease in any patients of any animal species (including human) associated with the presence of polymorphism cannot be readily deduced, even where the metabolic pathways are known. Further, each disease in any patients of any animal species (including human) associated with the presence of SNP has unpredictable effects on metabolic function, and no general method for a priori selection of diagnosis and drug

treatment is presented. It would require a large amount of experimentation, potentially including the synthesis of billions of chemicals (as only human genome consists of 60,000-100,000 polymorphic or variable sites), in order to identify additional metabolic pathways with the claimed functionality. Given the Wand's factors opposing the full scope of enablement including the limited teaching in the specification, the presence of only two hypothetical examples, the teaching of unpredictability in the prior art, the unpredictability of the art, the breadth of the claim, and the large amount of experimentation needed, with only the skill level in the art being neutral towards enablement, it is concluded that undue experimentation is necessary to make and use the invention as broadly claimed.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubin (U.S. patent 6,248,308 B1) (June 19, 2001).

Rubin teaches a composition of compounds effective for treating a pathology, the composition comprising at least two compounds (norastemizole and a leukotriene inhibitor) that modulate the activity of one or more target molecules associated with the pathology, wherein the combination is effective for at least one patient having the pathology (Abstract and Column 8, lines 1-21). Rubin inherently teaches that the target molecules are associated with one or more SNPs, wherein each compound modulates the activity of at least one target SNP. This inherency is borne out of the fact that it was known to an ordinary artisan at the time the invention was made that leukotriene mediated disease is caused by SNP, which can be effectively treated with leukotriene inhibitors (Morten, (U.S. Patent 6,316,196 B1) (November 13, 2001) (Column 7, line 57 to Column 8, line 28).

Rubin also teaches the composition, wherein the combination is inherently effective for at least 1% to 90% of patients having the pathology (Column 7, lines 11-19 and claims 1-24).

This rejection is based on the fact that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. Rubin inherently teaches the composition (Abstract and Column 8, lines 1-21); the interaction of the compound with the target molecule at a position corresponding to the SNP or at a position corresponding to a residue encoded by a codon comprising the SNP or modulation effect of each

compound and its correlation with the presence of a mutually exclusive SNP are intended use of the claimed composition, which is not given any further patentable weight. Moreover, at the time the invention was made it was known to an ordinary practitioner (as disclosed by Morten, Examples 1-3 and Column 8, lines 15-21) that the composition of the compound has the potential to interact with the target molecule at a position corresponding to the SNP or at a position corresponding to a residue or protein (LTC4 synthase) encoded by a codon comprising the SNP or the capability of modulation effect of each compound and its correlation with the presence of a mutually exclusive SNP. Morten also teaches the occurrence of mutually exclusive SNPs in a single or plurality of patients (Example 1) and at least two SNPs associated with one or two target molecules (Column 7, line 20 to Column 8, line 28).

Rubin teaches a composition comprising at least three to six compounds (Column 3, lines 28-38 and Claims 7, 16 and 22).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this

application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Chakrabarti,

Patent Examiner,

August 6, 2003

Arun kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER